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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/783,254	02/13/2001	Motasim Sirhan	020460000930	1701

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EXAMINER

PHAN, HIEU

ART UNIT PAPER NUMBER

3738

DATE MAILED: 02/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/783,254	Applicant(s) SIRHAN ET AL.	
	Examiner Hieu Phan	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38-44, 51-55, 57-61 and 63-65 is/are rejected.
- 7) ☒ Claim(s) 45-50, 56 and 62 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/08/2004</u> | 6) <input type="checkbox"/> Other: _____ |

Election/Restriction

1. The Election requirement in the Office Action that was mailed on 08/11/2004 has been withdrawn. An Office Action as follow:

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 42-44, 51-54, 58, 59, 60, 63 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ragheb et al. (U.S Patent 6,774,278) in view of Gregory et al. (U.S. Patent 5,283,257).

Ragheb et al. disclose a coated stent having porous layer 20 and 24 to control the release rate of drugs on the stent (column 11 lines 7-25 and column 14 lines 53-61). But Ragheb et al. further lacking the use of MPA and Mizoribine to treat vascular disease.

Gregory et al. disclose a method of treating hyperproliferation vascular disease by implanting a stent impregnated with MPA and Mizoribine. The advantage of using MPA and Mizoribine is to prevent restenosis at the site of the implant.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the teaching of Gregory et al. to modify the apparatus of Ragheb et al. to contain MPA and Mizoribine. The motivation for

Art Unit: 3738

incorporating the feature of Gregory et al. into the apparatus of Ragheb et al. is the drugs MPA and Mizoribine prevent restenosis at the site of the implant.

4. Claims 42-44, 51-53, 55, 57, 60, 61, 63 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ragheb et al. (U.S. Patent 6,774,278) in view of Wong (U.S. Patent 6,699,493).

Ragheb et al. disclose a coated stent having porous layer 20 and 24 to control the release rate of drugs on the stent (column 11 lines 7-25 and column 14 lines 53-61). But Ragheb et al. further lacking the use of mizoribine and methylprednisolone.

Wong disclose a method for reducing or preventing transplant rejection using an immunosuppressive agent such as mizoribine and a steroidal antiinflammatory agent such as methylprednisolone (column 4 lines 54-67, column 5 lines 4-7 and column 7 lines 15-34). The advantage of using the combination of mizoribine and methylprednisolone is to prevent the rejection of the implant.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the teaching of Wong to modify the apparatus of Ragheb et al. to contain mizoribine and methylprednisolone. The motivation for incorporating the feature of Gregory et al. into the apparatus of Ragheb et al. is to prevent the rejection of the implant.

5. Claims 38-41, 60 and 65 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gregory et al. (U.S. Patent 5,283,257).

Gregory et al. disclose method for treating hyperproliferation vascular disease by implanting a stent impregnated with a drug such as mizoribine and

Art Unit: 3738

releasing the drug once the stent is implanted (Abstract, column 3 lines 44-52, column 4 lines 17-31, column 6 lines 45-52 and column 12 lines 24-28 and 37-40).

Gregory et al. does not disclose expressly the rate of release of mizoribine between 5 microgram/day to 200 microgram/day, 10 microgram/day to 60 microgram/day, 1-45 days and 7-21 days.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to release of mizoribine between 5 microgram/day to 200 microgram/day, 10 microgram/day to 60 microgram/day, 1-45 days or 7-21 days, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In *re Aller*, 105 USPQ 233.

Allowable Subject Matter

6. Claim 45-50 and 56, 62 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

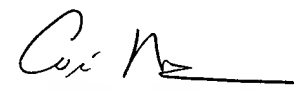
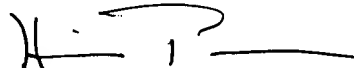
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hieu Phan whose telephone number is 571-272-4757. The examiner can normally be reached on Monday-Friday from 8am-5pm.

Art Unit: 3738

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hieu Phan
Examiner
Art Unit 3738



CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
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